1200 G Street NW, Suite 400
Washington, DC 20005-3814
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

AdvaMed
Advanced Medical Technology Association

July 18, 2000

***via* HAND DELIVERY**
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Ms. Carroll G. O'Neill
Ms. Catherine P. Wentz
Division of Cardiovascular, Respiratory and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Circulatory Support Prosthetics Group
Food and Drug Administration (HFZ-450)
9200 Corporate Boulevard
Rockville, MD 20850

RE: Medical Devices; Reclassification of 38 Preamendments Class III Devices into Class II; Comments on "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions," Docket Number 99N-0035

Dear Ms. O'Neill and Ms. Wentz:

We are writing on behalf of our client, the Advanced Medical Technology Association ("AdvaMed"), formerly the Health Industry Manufacturers Association to submit two copies of comments on FDA's "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions" in response to the Food and Drug Administration's ("FDA") request for such comments. AdvaMed coordinated and prepared these comments through a working group. The AdvaMed Working Group ("Working Group") includes the following members: Cobe Cardiovascular, Medtronic Perfusion Systems, and Terumo Cardiovascular Systems Corporation.

In March 1999, FDA published a proposed rule reclassifying 38 preamendments Class III devices into Class II and establishing special controls for these devices; among these devices was the Cardiopulmonary Bypass Oxygenator. See 64 Fed. Reg. 12774 (March 15, 1999). The Working Group concurs with FDA's proposed rule reclassifying these devices from Class III to Class II because the risks related to this device are well-characterized and well understood and

99N-0035

C8

special controls can reasonably assure the safety and effectiveness of the bypass oxygenator with regard to such risks.

In the above-referenced guidance issued by FDA on January 17, 2000, the agency proposed special controls for cardiopulmonary bypass oxygenators. On April 19, 2000, the agency reopened the comment period to the public to comment on the special controls described in FDA's guidance. See 65 Fed. Reg. 20933 (April 19, 2000). This comment is submitted pursuant to the April reopening of the comment period.

The Working Group recommends that FDA revise some of the special controls delineated in this guidance. For your convenience, we are describing the proposed changes in Attachment 1, and providing a clean copy of the guidance with the changes incorporated at Attachment 2.

Additionally, the Working Group thinks it is critical that the guidance address human factors issues and, therefore, recommends that FDA adopt the Centrifugal Pump Bypass ("CPB") Checklist as a special control and publish the checklist as part of the CPB Oxygenator guidance. A copy of the checklist is provided in Attachment 3.

If you have questions or need additional information about the proposed changes, please call Sandra Cohen Kalter at 202-626-2944 or Dianna Thomsen at 202-626-5594.

Sincerely,

Marlene K. Tandy/scr

Marlene K. Tandy, M.D., J.D.
Director Technology and Regulatory Affairs,
and Associate General Counsel

Of Counsel to AdvaMed:
Sandra Cohen Kalter, Esq.
Dianna Thomsen, Esq.
King & Spalding
1730 Pennsylvania Avenue, N.W.
Washington, DC 20006-4706